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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,963	01/28/2002	Andras Guttman	1360.038US1	4487

25297 7590 08/29/2005

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EXAMINER	
BARTON, JEFFREY THOMAS	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,963	GUTTMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Barton	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 29 June 2005 does not place the application in condition for allowance.

Status of Rejections Pending Since the Office Action of 27 December 2004

2. The rejection of claims 21-27 and 30-32 under 35 U.S.C. §102(b) as clearly anticipated by Strausbauch et al is withdrawn due to Applicant's amendment.

3. The rejection of claims 21, 27, 30, and 31 under 35 U.S.C. §103(a) as unpatentable over Lunte et al in view of Burd or Strausbauch et al is withdrawn due to Applicant's amendment.

4. The rejection of claims 28 and 29 under 35 U.S.C. §103(a) as unpatentable over Strausbauch in view of Karger et al is withdrawn due to Applicant's amendment.

5. The rejection of claims 21, 24, 37, 30 and 31 under 35 U.S.C. §102(b) as anticipated by Burd is maintained.

6. The rejection of claims 28 and 29 under 35 U.S.C. §103(a) as unpatentable over Burd in view of Karger et al is maintained.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 21, 24, 27, 30, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Burd.

The claims read on the operation of the embodiment of Burd illustrated in Figure 1. The "applying a sample" step recited in claim 21 reads on the function of sample reservoir 29. Specifically, Burd teaches (column 3, lines 41 to 43): "A sample reservoir **29** is included in the block (**28**) for sample introduction.". The "generating a migratory field" step recited in claim 21 reads on function of cathode **15**, anode **16**, and power source **17**. Regarding the "eluting" step and "collecting" step recited in claim 21 and the "analyzing" step recited in claim 24, Burd teaches (column 1, lines 50 to 54): "In the former, the segments are used to separate the species eluting from the larger capillary into *separate receptacles*, from which they may be separately recovered, *detected* treated or otherwise processed." (Italics added). Regarding the "interrupting the migratory field" step recited in claim 21, Burd teaches (column 4, lines 1 to 17): "In the embodiment shown in FIG. 1, it will be noted that the capillary segments **18** are spaced apart at intervals around the cassette **12**. The external openings **40** of the adjacent capillary segments are separated by portions of solid external wall **41**. In the arrangement shown, these intervening wall portions close off the separation capillary **11** and *interrupt the current path* whenever the capillary segments **18** not in alignment between the separation capillary **11** and the outlet buffer reservoir **14**. With the current path interrupted in this manner, the electrophoretic migration of solute species within the separation capillary **20** as well as all other portions of the apparatus is momentarily

suspended while the cassette rotates further and brings the next capillary segment into position. Thus, no components of the sample are lost and the entire elution profile will be distributed among the various capillary segments in the cassette". (Italics added) Additionally, Burd teaches that the capillaries may be moved relative to the collection vessels, instead of the collector moving relative to the stationary capillary (Column 2, line 66 - Column 3, line 4), which reads on the newly recited limitation that the separation pathway be removed from the collection well. The "collecting" step recited in claim 21 includes the limitation "without using a detector to analyze the analyte prior to collection". While the embodiment illustrated in Figure 1 shows a detector for analyzing the separated species prior to elution, this is an optional feature. Burd teaches (column 4, lines 59 to 61): "A variety of additional features *may* be incorporated into either of these systems. On-line detection, for example, *may* be achieved . . ." (Italics added). The "repeating" step recited in claim 21 reads on Burd (column 1, line 41-43): "The process may be repeated in an extended sequence, or as few times as once." The limitation recited in claim 24 reads on Burd (column 1, lines 46 to 54): "The invention has two primary embodiments, one in which the interchangeable segments are positioned at the downstream end of the larger, main body of the capillary, . . . the segments are used to separate the species into separate receptacles, from which they may be separately recovered, *detected*, treated or otherwise processed." The limitations recited in claims 27 and 30 read on Burd (claim 14, lines 14 to 21): "(c) moving said first and second structural members with respect to each other to place said capillary segments one at a time in alignment with said separation capillary; and (d)

upon alignment of each of said capillary segment with said separation capillary, imposing an electrical potential across the combined lengths of said separation capillary and the capillary segment aligned therewith." The limitation recited in claim 31 reads on Burd since the completely removing the electrical potential within the separation pathway constitutes "adjusting a potential within the separation pathway".

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 21-27 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strausbauch et al in view of either Lee et al [*J. Chromatogr. A.* 686 (1994) p. 309-317] or Rose et al [*J. Chromatogr.* 438 (1988) p. 23-34].

The "applying a sample" step, the "generating a migratory field" step, the "eluting an analyte" step and the "collecting the analyte" step recited in claim 21 and the limitation recited in claim 27 read on Strausbauch et al. because these steps occur in any preparative capillary electrophoretic separation (e.g. page 842, lines 19 to 21): "The low volume of a sample injection, requirement for fraction collection, and the unavoidable presence of high voltage (10-30 kV)". Although Strausbauch et al. does not explicitly state "collecting the analyte in a collection well without the using a detector to analyze the analyte prior to collection" (i.e., absence of an on-column detector), Strausbauch et al. does teach (page 849, lines 8 to 12): "Fraction collection routines can be programmed to collect a single component 'window' when the peak of interest and migration characteristics are known. Alternatively, fractions can be collected at fixed time intervals to collect the entire electrophoretic separation for recovery and assay of unknowns". Neither of these methods would require an on-column detector. The

"applying a sample" step and "generating a migratory field" step are inherent in any capillary electrophoretic separation. The limitations recited in claims 22 and 24 clearly read on the second method of Strausbauch et al. above. The limitation recited claims 23 and 32 clearly read on the first method of Strausbauch et al. above. Claim 31 reads on Strausbauch et al. since complete removal of the potential from the capillary (zero potential) constitutes an adjustment of the potential in the capillary. Regarding claims 25 and 26 see the section of Strausbauch et al. titled "Micro-preparative CE of Nucleic Acids" and the section of Strausbauch et al. titled "Micro-preparative CE of Peptides and Proteins".

In addition, Strausbauch et al cite the Rose et al and Lee et al references as disclosing suitable automated fraction collection methods. (Page 846 lines 7-13 and Section D on Automated Fraction Collection, pages 848-849)

Strausbauch et al do not explicitly describe a method wherein the migratory field is interrupted by removing the separation pathway from the collection well.

Lee et al describe a fraction collection method using a modified autosampler for collection, wherein the electric field is interrupted by the simultaneous removal of the capillary and electrode from the outlet vial. (Figure 2; Page 313, 1st column, lines 6-19)

Rose et al also describe a fraction collection method, wherein the electric field is interrupted by the removal of the capillary from the outlet vial. (Figure 3; Page 24, Fraction collector section - The description of "normal operation" in the third paragraph of this section does not recite a voltage shutdown, therefore the migratory field (i.e. electric field) is interrupted by the removal of the capillary.)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Strausbauch et al by providing a step whereby the migratory field is interrupted by removing the capillary from the collection well, as taught by Rose et al, Lee et al, or Guzman, because Strausbauch specifically cites the methods of Rose et al and Lee et al as appropriate ways of collecting fractions.

13. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd in view of Karger et al.

Regarding the teachings of Burd see the rejection based on this references above. Karger et al. is similar to Burd in that the detailed embodiment of Karger et al is directed to capillary electrophoresis including fraction collection. However, Karger teaches (page 5, lines 20 to 30): "The system of the invention will now be described in detail using as an example a system for the separation of fluorescently labeled DNA fragments by capillary electrophoresis; . . . Any method of separation could be employed, including but not limited to capillary electrophoresis (CE) . . . and capillary liquid chromatography (CLC). Capillary liquid chromatography involves creating a pressure differential between the ends of the capillary. This differential can be created by collecting one end of the capillary to either a source of pressure above ambient pressure ("applying a pressure to the separation pathway") or a source of pressure below ambient pressure ("drawing a vacuum in the separation pathway"). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of Burd or for fraction collection in capillary liquid chromatography even

though the disclosure of Burd explicitly discloses capillary electrophoresis because Karger et al. teaches that this is within the abilities of one skilled in the art.

14. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strausbauch et al and either Lee et al or Rose et al as applied to claim 21 above, and further in view of Karger et al.

The reasoning for this rejection parallels that given above in paragraph 13.

Response to Arguments

15. Applicant's arguments filed on 29 June 2005 have been fully considered but they are not persuasive.

Applicant argued that the new limitation that the migratory field be interrupted "by removing the output end of the separation pathway from the collection well" patentably distinguished the instant claims from the prior art applied in the previous rejections. However, contrary to Applicant's contention, Burd discloses a collection method that reads on this new limitation, as described in the rejection above. Additionally, the Examiner considers this limitation to be an obvious modification to the methods disclosed by Strausbauch et al, as described in the rejection above.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

JTB
25 August 2005

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